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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,884	07/02/2003	Michael Houghton	PP19545.003	6634

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,884	HOUGHTON, MICHAEL	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 19-21, drawn to a method of stimulating an immune response comprising administering the composition comprising a fusion protein comprising a modified NS3 polypeptide and an Hepatitis C virus (HCV) polypeptide other than NS3, classified in class 435, subclass 5.

II. Claims 25-40, drawn to a polynucleotide comprising a coding sequence encoding a fusion protein comprising a modified NS3 polypeptide and a Hepatitis C virus (HCV) polypeptide other than NS3, classified in class 536, subclass 23.1.

Further restriction is required if Groups I or II are elected. Applicant must elect one embodiment from claim 13(a)-(j) and claim 14 (a)-(j), and the embodiment must be the same for claims 13 and 14.

Claims 1, 11, 12, 16-18 and 22-24 link(s) inventions III-XIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 11, 12, 16-18 and 22-24. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the

instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

III. Claims 2 and 15, drawn to a fusion protein comprising a modified NS3 polypeptide and an Hepatitis C virus (HCV) polypeptide other than NS3, wherein the modification to the NS3 polypeptide comprises an amino acid substitution corresponding to His-1083, Asp-1105 and/or Ser-1165, classified in class 424, subclass 192.1.

IV. Claims 3, 13(a) and 14(a), drawn to a fusion protein comprising a modified NS3 polypeptide, an NS4 polypeptide, an NS5a polypeptide and optionally a core polypeptide, classified in class 424, subclass 192.1.

V. Claims 4, 13(b) and 14(b), drawn to a fusion protein comprising a modified NS3 polypeptide, an NS4 polypeptide, an NS5a polypeptide, an NS5b polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

VI. Claims 5, 13(c) and 14(c), drawn to a fusion protein comprising a modified NS3 polypeptide, an E2 polypeptide, a p7 polypeptide, an NS2 polypeptide, an NS4 polypeptide, an NS5a polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

VII. Claims 6, 13(d) and 14(d), drawn to a fusion protein comprising a modified NS3 polypeptide, an E1 polypeptide, an E2 polypeptide, a p7 polypeptide, an NS2 polypeptide, an NS4 polypeptide, an NS5a polypeptide, and optionally a core polypeptide, classified in 424, subclass 192.1.

VIII. Claims 7, 13(e) and 14(e), drawn to a fusion protein comprising a modified NS3 polypeptide, an E2 polypeptide, an NS4 polypeptide, an NS5a polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

IX. Claims 8, 13(f) and 14(f), drawn to a fusion protein comprising a modified NS3 polypeptide, an E1 polypeptide, an E2 polypeptide, an NS4 polypeptide, an NS5a polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

X. Claims 9, 13(g) and 14(g), drawn to a fusion protein comprising a modified NS3 polypeptide, an E2 polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

XI. Claims 10, 13(h) and 14(h), drawn to a fusion protein comprising a modified NS3 polypeptide, an E1 polypeptide, an E2 polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

XII. Claims 13(i) and 14(i), drawn to a fusion protein comprising a modified NS3 polypeptide, an E2 polypeptide, a p7 polypeptide, an NS2 polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

XIII. Claims 13(j) and 14(j), drawn to a fusion protein comprising a modified NS3 polypeptide, an E1 polypeptide, an E2 polypeptide, a p7 polypeptide, an NS2 polypeptide, and optionally a core polypeptide, classified in class 424, subclass 192.1.

2. The inventions are distinct, each from the other because of the following reasons:

i) Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of stimulating an immune response by administering a fusion polypeptide, and a DNA encoding a fusion polypeptide. These inventions are not disclosed as capable of use together, nor do they share modes of operation, function or effect. DNA and associated vectors and host cells are not disclosed as being administered to an individual to induce an immune response. A search for both the DNA and the method of using the encoded peptide would be a serious burden because literature that speaks to the DNA will not necessarily reveal methods of inducing an immune response.

ii) Inventions I and (III-XIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in method of detecting antibodies to various proteins of HCV. Detecting antibodies is a materially different method than administering fusion proteins. A search for both the method of using the fusion protein and the fusion protein itself would be a serious burden.

iii) Inventions III-XIII and inventions of embodiments (a)-(j) of claims 13 and 14 are distinct products. The products are comprised of different protein units that form a fusion protein. The different protein units are comprised of NS2, NS3, NS4, NS51, NS5b, p7, E1, E2 and a core polypeptide. Inventions III-XIII are drawn to various combinations of proteins from

HCV, which would be a serious burden to search. The same reasoning applies of the embodiments (a)-(j) of claims 13 and 14, all of which are drawn to different combinations of HCV structural units. The amino acid structures and/or DNA structures of each of the proteins are different, and encode different proteins/peptides. Mixing and matching different peptides results in products that have different immunological capabilities. For example, a fusion peptide comprising NS3 and E2 will have a different immunological effect than a fusion peptide comprising NS3, NS4 and NS5. The functions and effects of the different fusion proteins are substantial because the different proteins elicit different immune responses (different antibodies, for example).

Because these inventions are distinct for the reasons given above and the literature search required for one group is not required or is not co-extensive for any other group and therefore a serious search burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In summary, Applicant must elect one invention from the Groups listed as I-XIII. If Applicant elects Group I or Group II, further restriction is required; Applicant must pick one embodiment from claims 13 and 14, (a)-(j). If Applicant elects one of Groups III-XIII, linking claims 1, 11, 12, 16-18 and 22-24 will be examined along with the claim(s) listed in the elected Group. Should Applicant have any questions about this restriction requirement, please contact the Examiner for clarification.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

4. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
February 22, 2005